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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,578	11/05/2003	Tae-Wan Kim	5199-14	9442

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EXAMINER	
BALLARD, KIMBERLY A	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/702,578	KIM ET AL.	
	Examiner	Art Unit	
	Kimberly A. Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-93* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I-XI. Claims 1-6, 18-22, and 24-25 (each in part), drawn to a nucleic acid sequence of SEQ ID NO: 1, 2, 3, 7, 9, 11, 13, 15, 17, 18, and 20 encoding a polypeptide, wherein the polypeptide is presenilin stabilization factor (PSF) or PSF-like protein (PSFL), vectors and host cells comprising the nucleic acid, and a method of making the polypeptide, classified for example in class 536, subclass 23.1 and class 435, subclass 320.1, 325.

XII-XXIII. Claims 7-12 (each in part), drawn to a purified polypeptide (PSF or PSFL) of SEQ ID NO. 4, 5, 6, 8, 10, 12, 14, 16, 19, 21, and 70, and pharmaceutical compositions comprising same, classified for example in class 530, subclass 350.

XXIV. Claims 13-17, drawn to an antibody specific for PSF or PSFL and a method of producing the antibody comprising immunizing a mammal with the selected polypeptide, classified for example in class 530, subclass 387.1.

XXV. Claim 23, drawn to a transgenic animal containing the host cell of Invention I, classified for example in class 800, subclass 13.

XXVI. Claims 31, 49, and each of 26-30 and 43-48 in part, drawn to a method of decreasing amyloid-beta production *in vitro*, classified for example in class 435, subclass 4.

XXVII. Claims 26-29, 32-33, 36-41, 43-48, 50-52, 55-59, 61-64, and 68-72 each in part, drawn to a method for treating neurodegeneration in a subject, comprising administering a peptide or peptide modulator which decreases amyloid-beta production, classified for example in class 514, subclass 1.

XXVIII. Claims 34-35, 53-54, 65-67, 73-74, and each of 26-30, 32-33, 36-41, 43-48, 50-52, 55-59, 61-64, and 68-72 in part, drawn to a method for treating neurodegeneration in a subject, comprising administering a modulator of amyloid-beta production via gene therapy, classified for example in class 514, subclass 44.

XXIX. Claims 42 and 60, drawn to a pharmaceutical composition for decreasing amyloid-beta production comprising a pharmaceutically-acceptable carrier and an inhibitor of PSF or PSFL, or a rhomboid peptide, classified for example in class 514, subclass 2.

XXX. Claims 75-79, drawn to an *in vitro* system and method of making an *in vitro* system for identifying agents that selectively modulate production of Aβ or APP, classified for example in class 435, subclass 348.

XXXI. Claims 80 and 87, drawn to a method for identifying agents that selectively modulate production of Aβ or APP, classified for example in class 435, subclass 6.

XXXII. Claims 81-82 and 88-89, drawn to an agent that modulates Aβ or APP, classified for example in class 530, subclass 350.

XXXIII. Claims 83-86 and 90-93, drawn to a method for treating neurodegeneration in a subject, comprising administering an agent of Invention XI, classified for example in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XXV, XXIX-XXX, and XXXII are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions I-XXV, XXIX-XXX, and XXXII are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acids of Inventions I-XI are each structurally and functionally distinct from each other. Further, the nucleic acids of Inventions I-XI, antibody of Invention XXIV, transgenic animal of Invention XXV, pharmaceutical composition of Invention XXIX, and agent of Invention XXXI are not recited or required by each other or any of the other Inventions XII-XXIII or XXX. The polypeptides of Inventions XII-XXIII are each structurally distinct, and they are structurally and functionally distinct from the pharmaceutical composition of Invention XXIX, the *in vitro* system of Invention XXX, the nucleic acid sequences of Inventions I-XI, antibody of XXIV, transgenic animal of XXV, and agent of XXXI.

Inventions XXVI-XXVIII, XXXI and XXXIII are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, Inventions XXVI-XXVIII, XXXI and XXXIII are directed to methods that are distinct from each other in reagents, steps, and outcomes or functions, and are not required one for the other. For example, the methods of Inventions XXVII, XXVIII and XXXIII recite administration of an agent to a subject, which is not required by Inventions XXVI or XXXI. Further, Invention XXVIII recites the administration of nucleic acids, whereas Invention XXVII administers peptides and Invention XXXIII administers protein found by a screening method. The methods of Invention XXXI involve the use of cultured insect cells, which are not recited by the methods of Invention XXVI.

Inventions (I-XXV, XXX and XXXII) and (XXVI-XXVIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-XXV, XXX and XXXII and each of Groups XXVI-XXVIII are unrelated products and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions XXVI-XXVIII do not recite the use or production of the products of Inventions I-XXV, XXX and XXXII.

Inventions (I-XXV) and (XXXI and XXXIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups I-XXV and each of Groups XXXI and XXXIII are unrelated products and processes, wherein each is not required, one for another. For example, the claimed method of Inventions XXXI and XXXIII does not recite the use or production of the products of Inventions I-XXV.

Inventions XXIX and XXVII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for treating neurodegeneration could be practiced with another product, such as an anti-amyloid-beta antibody. The product as claimed could be used to immunize animals to generate antibodies for diagnostic use.

Inventions XXIX and each of XXVI, XXVIII, XXXI, and XXXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group XXIX and each of Groups XXVI, XXVIII, XXXI, and XXXIII are unrelated product and processes, wherein each is not required, one for another. For example, the

claimed methods of Inventions XXVI, XXVIII, XXXI, and XXXIII do not recite the use or production of the pharmaceutical composition of Inventions XXIX.

Inventions XXX and XXXI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of Invention XXXI could be practiced with neuronal-like cells (such as PC-12 cells) or with primary neuronal cultures instead of the *Drosophila*-derived S2 cells recited in Invention XXX.

Inventions XXX and XXXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group XXX and Group XXXIII are unrelated product and process, wherein each is not required, one for another. For example, the claimed method of Invention XXXIII does not recite the use or production of the *in vitro* system of Invention XXX.

Inventions XXXII and XXXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Group XXXII and Group XXXI are unrelated product and process, wherein each is not required, one for another. For

example, the claimed method of Invention XXXI does not recite the use or production of the agent of Invention XXXII.

Inventions XXXII and XXXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method for treating neurodegeneration in a subject could be practiced with another product, such as an anti-amyloid-beta antibody. The product as claimed could be used to immunize animals to generate antibodies for diagnostic use.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for and group is not required for any other group, restriction for examination purposes as indicated is proper.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention: neurodegenerative conditions or diseases. The following diseases and conditions are patentably distinct both etiologically and

functionally and require separate search and consideration of distinct patient populations:

a. Alzheimer's disease

b. amyotrophic lateral sclerosis (Lou Gehrig's Disease)

c. Binswanger's disease

d. corticobasal degeneration (CBD)

e. dementia lacking distinctive histopathology (DLDH)

f. frontotemporal dementia (FTD)

g. Huntington's chorea

h. multiple sclerosis

i. myasthenia gravis

j. Parkinson's disease

k. Pick's disease

l. progressive supranuclear palsy (PSP)

Because these species are distinct for the reasons given above and the search required for one disease or condition is not required for any other disease or condition, election of species for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 38, 56, 61, 68, 83, and 90 are generic.

If applicant selects Invention XXVII, XXVIII, or XXXIII, one species from the disease group (a-l) must be chosen to be fully responsive.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product

claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Ballard whose telephone number is 571-272-4479. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kimberly Ballard, PhD
Art Unit 1649
December 14, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER